Open-Label Extension Study of 23 mg Donepezil SR in Patients With Moderate to Severe Alzheimer's Disease

This study has been completed.

Sponsor:
Eisai Inc.

Collaborator:
Eisai Limited

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT00566501

First received: November 29, 2007
Last updated: June 26, 2014
Last verified: May 2012
History of Changes

Results First Received: May 16, 2012

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Alzheimer's Disease
Interventions:	Drug: 23 mg SR in Study 326 Drug: 10 mg IR in Study 326

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

This study was recruited at 179 centers in Asia, Europe, North America, Oceania, South Africa, and South America during the period of 14 December 2007 to 01 April 2010.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

This study (E2020-G000-328) was a 12-month, open-label extension of study E2020-G000-326. Subjects who had received donepezil 10 mg IR or donepezil 23 mg IR during Study 326 were eligible for enrollment into this study.

Reporting Groups

	Description
23 mg SR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.
10 mg IR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.

Participant Flow: Overall Study

	23 mg SR in Study 326	10 mg IR in Study 326
STARTED	**579**	**336**
Safety Population	**570**	**332**
Discontinued	**146**	**122**
Adverse Event	**68**	**59**
Lack of Efficacy	**8**	**3**
Withdraw of Consent by Subject	**33**	**30**
Request of Investigator or Sponsor	**6**	**7**
Protocol Violation	**2**	**2**
Medication Non-compliance	**5**	**0**
Other (Not Specified)	**24**	**21**
Not Determined	**1**	**0**
COMPLETED	**423**	**210**
NOT COMPLETED	**156**	**126**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
23 mg SR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.
10 mg IR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.
Total	Total of all reporting groups

Baseline Measures

	23 mg SR in Study 326	10 mg IR in Study 326	Total
Overall Participants Analyzed [Units: Participants]	**579**	**336**	**915**

Age [Units: Years] Mean (Standard Deviation)	**74.1 (8.63)**	**74.5 (8.46)**	**74.2 (8.56)**
Gender [Units: Participants]			
Female	**378**	**204**	**582**
Male	**201**	**132**	**333**
Race/Ethnicity, Customized [Units: Participants]			
American Indian or Alaska Native	**0**	**0**	**0**
Asian	**82**	**62**	**144**
Black or African American	**17**	**7**	**24**
White	**435**	**246**	**681**
Other (not specified)	**3**	**2**	**5**
Hispanic	**42**	**19**	**61**

Outcome Measures

1. Primary: Long-term Safety as Measured by Incidence of Adverse Events During the 12 Month Treatment Period [Time Frame: Throughout the study (12 months for all AEs and up to an additional 30 days for SAEs)]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Long-term Safety as Measured by Incidence of Adverse Events During the 12 Month Treatment Period
Measure Description	Adverse events (AEs), including SAEs, were recorded from the time of consent. Recording of AEs ceased after the Final Visit or Early Termination Visit, except that SAEs were monitored for 30 days after study drug discontinuation.
Time Frame	Throughout the study (12 months for all AEs and up to an additional 30 days for SAEs)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Safety Population consisted of all subjects who received at least one dose of donepezil SR 23 mg during Study 328. Two groups were categorized: those who received donepezil 10 mg IR and those who received donepezil 23 mg SR during Study 326.

Reporting Groups

	Description
23 mg SR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.
10 mg IR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.

Measured Values

	23 mg SR in Study 326	**10 mg IR in Study 326**
Participants Analyzed [Units: Participants]	**570**	**332**

Long-term Safety as Measured by Incidence of Adverse Events During the 12 Month Treatment Period [Units: Participants]	**570**	**332**

No statistical analysis provided for Long-term Safety as Measured by Incidence of Adverse Events During the 12 Month Treatment Period

2. Secondary: Mean Change From Baseline in MMSE Score [Time Frame: 12 months]
Results not yet reported. Anticipated Reporting Date: No text entered. **Safety Issue:** No

3. Secondary: Mean Change From Baseline in SIB Score [Time Frame: 12 months]
Results not yet reported. Anticipated Reporting Date: No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
23 mg SR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.
10 mg IR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.

Serious Adverse Events

	23 mg SR in Study 326	**10 mg IR in Study 326**
Total, serious adverse events		
# participants affected / at risk	**80/570 (14.04%)**	**56/332 (16.87%)**
Blood and lymphatic system disorders		
Anemia		
# participants affected / at risk	**1/570 (0.18%)**	**0/332 (0.00%)**
Cardiac disorders		
Acute myocardial infarction		
# participants affected / at risk	**0/570 (0.00%)**	**1/332 (0.30%)**
Angina pectoris		
# participants affected / at risk	**1/570 (0.18%)**	**0/332 (0.00%)**
Arrhythmia supraventricular		
# participants affected / at risk	**0/570 (0.00%)**	**1/332 (0.30%)**
Atrial fibrillation		
# participants affected / at risk	**0/570 (0.00%)**	**2/332 (0.60%)**
Bradycardia		
# participants affected / at risk	**2/570 (0.35%)**	**0/332 (0.00%)**
Cardiac failure		
# participants affected / at risk	**1/570 (0.18%)**	**1/332 (0.30%)**
Myocardial infarction		

# participants affected / at risk	2/570 (0.35%)	0/332 (0.00%)
Ventricular tachycardia		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Cardio-respiratory arrest		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Cardio-rspiratory arrest		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Congenital, familial and genetic disorders		
Encephalocele		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hydrocele		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Meningocele		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Gastrointestinal disorders		
Abdominal pain		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Diarrhoea		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Duodenal ulcer		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Gastric ulcer		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Gastrointestinal hemorrhage		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Haematemesis		
# participants affected / at risk	0/570 (0.00%)	2/332 (0.60%)
Haematochezia		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Ileus paralytic		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Oesophageal ulcer		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Pancreatic mass		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Upper gastrointestinal hemorrhage		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
vomiting		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
General disorders		
Asthenia		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Chest pain		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Death		
# participants affected / at risk	2/570 (0.35%)	0/332 (0.00%)
Gait disturbance		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Multi-organ failure		

# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Non-cardiac chest pain		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Sudden death		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hepatobiliary disorders		
Cholecystitis acute		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hepatic cirrhosis		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Infections and infestations		
Abdominal abscess		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Bronchitis		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Cellulitis staphylococcal		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Gastroenteritis		
# participants affected / at risk	2/570 (0.35%)	0/332 (0.00%)
Liver abscess		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Lobar pneumonia		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Lower respiratory tract infection		
# participants affected / at risk	2/570 (0.35%)	0/332 (0.00%)
Orchitis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Peritonillar abscess		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
pneumonia		
# participants affected / at risk	6/570 (1.05%)	1/332 (0.30%)
Respiratory tract infection		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Sepsis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Tuberculosis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Urinary tract infection		
# participants affected / at risk	8/570 (1.40%)	3/332 (0.90%)
Injury, poisoning and procedural complications		
Concussion		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Device lead damage		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Dislocation of joint prosthesis		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Fall		
# participants affected / at risk	7/570 (1.23%)	2/332 (0.60%)
Femoral neck fracture		

# participants affected / at risk	3/570 (0.53%)	0/332 (0.00%)
Femur fracture		
# participants affected / at risk	2/570 (0.35%)	0/332 (0.00%)
Head injury		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Hip fracture		
# participants affected / at risk	2/570 (0.35%)	1/332 (0.30%)
Laceration		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Lumbar vertebral fracture		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Radius fracture		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Road traffic accident		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Skin laceration		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Subdural haematoma		
# participants affected / at risk	1/570 (0.18%)	3/332 (0.90%)
Thoracic vertebral fracture		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Upper limb fracture		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Subdural haemorrhage		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Investigations		
Electrocardiogram QT prolonged		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Lipase increased		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Weight decreased		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Metabolism and nutrition disorders		
Anorexia		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Dehydration		
# participants affected / at risk	2/570 (0.35%)	3/332 (0.90%)
Gout		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hypokalaemia		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Hyponatremia		
# participants affected / at risk	0/570 (0.00%)	2/332 (0.60%)
Musculoskeletal and connective tissue disorders		
Muscle rigidity		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Osteoarthritis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		

Breast cancer		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Lung carcinoma cell type unspecified stage IV		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Lung neoplasm		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Malignant melanoma		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Metastases to liver		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Metastases to spine		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Metastasis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Prostate cancer		
# participants affected / at risk	0/570 (0.00%)	2/332 (0.60%)
Prostate cancer stage II		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Rectal cancer		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Lung neoplasm malignant		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Nervous system disorders		
Bradykinesia		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Cerebral atrophy		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Cerebral hemorrhage		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Cerebral infarction		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Cerebrospinal fistula		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Cerebrovascular accident		
# participants affected / at risk	5/570 (0.88%)	2/332 (0.60%)
Convulsion		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Dementia Alzheimers type		
# participants affected / at risk	2/570 (0.35%)	0/332 (0.00%)
# events	570	
Dizziness		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Encephalopathy		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Epilepsy		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Headache		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hemiparesis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)

Hemiplegia		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hydrocephalus		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Ischemic cerebral infarction		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Lacunar infarction		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Presyncope		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Sciatica		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Status epilepticus		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Syncope		
# participants affected / at risk	6/570 (1.05%)	6/332 (1.81%)
Transient ischemic attack		
# participants affected / at risk	1/570 (0.18%)	3/332 (0.90%)
Unresponsive to stimuli		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Psychiatric disorders		
Aggression		
# participants affected / at risk	1/570 (0.18%)	3/332 (0.90%)
Agitation		
# participants affected / at risk	0/570 (0.00%)	2/332 (0.60%)
Anxiety		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hallucination		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Insomnia		
# participants affected / at risk	0/570 (0.00%)	3/332 (0.90%)
Mental status change		
# participants affected / at risk	0/570 (0.00%)	4/332 (1.20%)
Poriomania		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Psychotic disorder		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Restlessness		
# participants affected / at risk	1/570 (0.18%)	2/332 (0.60%)
Renal and urinary disorders		
Calculus bladder		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Haematuria		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Nephrolithiasis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Neurogenic bladder		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Renal failure		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)

Urinary retention		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Renal failure acute		
# participants affected / at risk	1/570 (0.18%)	2/332 (0.60%)
Reproductive system and breast disorders		
Benign prostatic hyperplasia		
# participants affected / at risk	2/570 (0.35%)	0/332 (0.00%)
Prostatomegaly		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Choking		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Chronic obstructive pulmonary disease		
# participants affected / at risk	1/570 (0.18%)	1/332 (0.30%)
Dyspnea		
# participants affected / at risk	3/570 (0.53%)	0/332 (0.00%)
Lung disorder		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Pleural effusion		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Pulmonary embolism		
# participants affected / at risk	0/570 (0.00%)	2/332 (0.60%)
Vascular disorders		
Deep vein thrombosis		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)
Hypertension		
# participants affected / at risk	0/570 (0.00%)	1/332 (0.30%)
Hypotension		
# participants affected / at risk	1/570 (0.18%)	0/332 (0.00%)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	2

Reporting Groups

	Description
23 mg SR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.
10 mg IR in Study 326	Donepezil SR 23 mg once daily orally for 12 months to patients who either (a) received donepezil 23 mg SR in the preceding double-blind study E2020-G000-326, or (b) received donepezil 10 mg IR in that study.

Other Adverse Events

	23 mg SR in Study 326	10 mg IR in Study 326
Total, other (not including serious) adverse events		
# participants affected / at risk	415/570 (72.81%)	259/332 (78.01%)
Blood and lymphatic system disorders		
Anaemia		
# participants affected / at risk	2/570 (0.35%)	9/332 (2.71%)
Gastrointestinal disorders		
Diarrhoea		
# participants affected / at risk	19/570 (3.33%)	18/332 (5.42%)
Insomnia		
# participants affected / at risk	18/570 (3.16%)	12/332 (3.61%)
Vomiting		
# participants affected / at risk	9/570 (1.58%)	14/332 (4.22%)
Constipation		
# participants affected / at risk	6/570 (1.05%)	8/332 (2.41%)
General disorders		
Nausea		
# participants affected / at risk	12/570 (2.11%)	20/332 (6.02%)
Irritability		
# participants affected / at risk	13/570 (2.28%)	7/332 (2.11%)
Oedema peripheral		
# participants affected / at risk	15/570 (2.63%)	5/332 (1.51%)
Asthenia		
# participants affected / at risk	5/570 (0.88%)	11/332 (3.31%)
Infections and infestations		
Nasopharyngitis		
# participants affected / at risk	14/570 (2.46%)	11/332 (3.31%)
Injury, poisoning and procedural complications		
Fall		
# participants affected / at risk	47/570 (8.25%)	23/332 (6.93%)
Contusion		
# participants affected / at risk	9/570 (1.58%)	7/332 (2.11%)
Investigations		
Weight decreased		
# participants affected / at risk	57/570 (10.00%)	43/332 (12.95%)
Weight increased		
# participants affected / at risk	15/570 (2.63%)	12/332 (3.61%)
Metabolism and nutrition disorders		
Anorexia		
# participants affected / at risk	11/570 (1.93%)	10/332 (3.01%)
Hypercholesterolaemia		
# participants affected / at risk	10/570 (1.75%)	7/332 (2.11%)
Musculoskeletal and connective tissue disorders		
Arthralgia		
# participants affected / at risk	7/570 (1.23%)	8/332 (2.41%)

Nervous system disorders		
Syncope		
# participants affected / at risk	**13/570 (2.28%)**	**3/332 (0.90%)**
Dizziness		
# participants affected / at risk	**5/570 (0.88%)**	**11/332 (3.31%)**
Psychiatric disorders		
Agitation		
# participants affected / at risk	**33/570 (5.79%)**	**26/332 (7.83%)**
Aggression		
# participants affected / at risk	**28/570 (4.91%)**	**20/332 (6.02%)**
Depression		
# participants affected / at risk	**15/570 (2.63%)**	**12/332 (3.61%)**
Anxiety		
# participants affected / at risk	**12/570 (2.11%)**	**2/332 (0.60%)**
Renal and urinary disorders		
Urinary tract infection		
# participants affected / at risk	**25/570 (4.39%)**	**18/332 (5.42%)**
Urinary incontinence		
# participants affected / at risk	**12/570 (2.11%)**	**11/332 (3.31%)**
Respiratory, thoracic and mediastinal disorders		
Cough		
# participants affected / at risk	**7/570 (1.23%)**	**7/332 (2.11%)**
Vascular disorders		
Hypertension		
# participants affected / at risk	**18/570 (3.16%)**	**9/332 (2.71%)**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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Responsible Party:	Eisai Inc.
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